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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,773	11/14/2001	Kiamars Hajizadeh	3873 P 011	1833

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/26/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/990,773

Applicant(s)

HAJIZADEH, KIAMARS

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

1. Claims 1-34 are pending and under consideration.

#### **Drawings**

2. Figure 1 is objected to as failing to comply with 37 CFR 1.84(p)(5) because it includes the following reference sign not mentioned in the description: 28.

Figure 4 is objected to as failing to comply with 37 CFR 1.84(p)(5) because it includes the following reference sign not mentioned in the description: 312.

Figure 3 is objected to as failing to comply with 37 CFR 1.84(p)(5) because it does not include the following reference sign mentioned in the description, page 14, line 17: 228.

A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### **Specification**

3. The disclosure is objected to because of the following informalities:
  - a) page 5, line 24, the description recites "Figure 2 is a side perspective", but Figure 2 appears to be a view from a top perspective,
  - b) page 6, line 1, the description recites "Figure 3 is a top schematic view", but Figure 3 appears to be a view from a side perspective,
  - c) page 11, line 15, recites "a strip support 13", but none of the figures show any component labeled "13",

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d) page 14, line 17, recites "a spacer pad 228", but none of the figures show any component labeled "228 ",

Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 3-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of detecting prion disease utilizing antibodies specific for PrP<sup>Sc</sup>, does not reasonably provide enablement for detecting all other diseases in animal carcasses. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a

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disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - a method of detecting any/all disease in animal carcasses comprising: 1) terminating an animal, assaying a treated sample with antibodies specific to a marker of the disease, correlating test result to the animal.

The state of the prior art is high for a number of animal disease detection methods.

The amount of direction/guidance/working examples present - the instant specification provides limited guidance for a method for detection of one disease, prion infection. The instant specification does not provide sufficient guidance nor working examples commensurate in scope with the instant claims.

Thus, the quantity of experimentation necessary to adapt the instant claims to all other diseases in animal carcasses constitutes merely an invitation to experiment without a reasonable expectation of success.

7. Claims 1-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of prion disease utilizing antibodies which are specific for PrP<sup>SC</sup>, does not reasonably provide enablement for distinguishing between diseased and nondiseased carcasses by detecting merely prion protein using antibodies other than those

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specific for PrP<sup>SC</sup>. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention -a method of detecting prion disease in animal or humans comprising: 1) obtaining a sample, assaying a treated sample with antibodies specific to a marker of the disease, correlating test result to the animal/human.

The state of the prior art for prion disease detection is improving with new specific antibodies and assays. However, the predictability in the art of prion disease diagnosis highly depends on the specificity of the antibodies to the disease conformation of PrP.

The instant specification provides no actual working examples of the claimed inventions, only parameters of sample handling and procedures which applicants indicate should result in the claimed invention. Such prophetic language is insufficient guidance to enable one of ordinary skill in the art to perform the required diagnostic methods without undue experimentation.

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The claimed invention relies on antibodies specific PrP<sup>SC</sup>, with one antibody binding to one epitope of PrP<sup>SC</sup>, while a second antibody binds to another epitope of PrP<sup>SC</sup>. However, the instant specification provides no examples of the two antibodies.

Thus, the instant claims constitute merely an invitation to experiment, without a reasonable expectation of success.

8. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of detecting disease in animal carcasses and according to step (g), correlating the test result to the animal so the carcass having a positive **or** negative test result may be removed. It is unclear what is being claimed if all carcasses are removed, i.e., whether positive or negative for disease.

9. Claim 4 is rejected under 35 U.S.C. 112, second paragraph, lack of antecedent basis, because the claim recites the limitation "extract the prion protein" from the sample of method claim 1 in line 2. There is insufficient antecedent basis for this limitation in the claim because claim 1 does not recite "prion protein".

10. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claim is unclear because it ends with "for subsequent fastening thereto of the at least a portion the test device". The word "of" appears to be missing from between "portion" and "the".

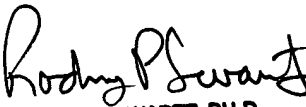
### Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.

  
RODNEY P SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

March 24, 2003